IFW

DOCKET NO.: JJPR-0048 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Wing K. Cheung, et al. **Confirmation No.: 1406**

Application No.: 10/775,928 **Group Art Unit: 1614**

Filing Date: February 10, 2004 **Examiner: Not Yet Assigned**

For: PHARMACEUTICAL COMPOSITIONS OF ERYTHROPOIETIN

DATE OF DEPOSIT: November 1, 2004

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

Elizabeth A. McLoud

TYPED NAME: Elizabeth A. McLoud

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

☒ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of

the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.116 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

- ☐ Certification in Accordance with § 1.97(e) is attached; or
- ☐ The fee of **$180.00** as set forth in § 1.17(p) is attached.

☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of **$180.00** as set forth in § 1.17(p).

☒ Copies of reference numbers **29 - 35** listed on the attached Form PTO-1449 are enclosed herewith.

☒ Copies of reference numbers **23 - 24** on the attached Form PTO 1449 are not required to be submitted pursuant to 37 CFR § 1.98(a)(2)(i).

- ☒ Copies of references **1 – 22, 25 - 28** are not being submitted because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application number **09/545,479**, filed **April 7, 2000** for which a claim for priority under 35 U.S.C. § 120 has been made in the instant application.

☐ The relevance of those listed references which are not in the English language is as follows:

There are no listed references which are not in the English language.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

Date: October 29, 2004

Felicity E. Groth
Registration No. 47,042

WOODCOCK WASHBURN LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. JJPR-0048	Application No. 10/775,928
	Applicant Wing K. Cheung, et al.	
	Filing Date February 10, 2004	Group 1614
	Confirmation No. 1406	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	1	Ateshkadi, A., et al., "Pharmacokinetics of intraperitioneal, and subcutaneous recombinant human erythropoietin in patients on continuous ambulatory peritoneal dialysis," *Am. J. of Kidney Dis.*, **1993**, *21(6)*, 635-642
	2	Breymann, C., et al., " Optimal timing of repeated rh-erythropoietin administration improves its effectiveness in stimulating erythropoiesis in healthy volunteers," *British J. of Haemotology*, **1996**, *92*, 295-301
	3	Egrie, J.C., et al., "Characterization and biological effects of recombinant human erythropoietin," *Immunobiol.*, **1986**, *172*, 213-224
	4	Faulds, D., et al., "A review of its pharmacodynamic and pharmacokinetic properties and therapeutic potential in anaemia and the stimulation of erythropoiesis," *Drugs*, **1989**, *38(6)*, 863-899
	5	Frenken, L.A.M., et al., "Identification of the component part in an epoietin alfa preparation that causes pain after subcutaneous injection," *Am. J. of Kidney Dis.*, **1993**, *22(4)*, 553-556
	6	Granolleras, C., et al., "Experience of pain after subcutaneous administration o different preparations of recombinant human erythropoietin: a randomized, double-blind crossover study," *Clinical Nephrology*, **1991**, *36(6)*, 294-298
	7	Halstenson, C., et al., "Comparative pharmacokinetics and pharmacodynamics of epoetin alfa and epoietin alfa and epoietin alfa and epoietin beta," *Clin. Pharmacol. Ther.*, **1991**, *50*, 702-712
	8	Jacobs, K., et al., "Isolation and characterization of genomic and cDNA clones of human erythropoietin," *Nature*, **1985**, *313*, 806-810
	9	Jelkmann, W., Erythropoietin: Structure, Control of Production, and Function, *Physiological Rev.*, **1992**, *72(2)*, 449-489
	10	Koury, S., et al., "Localization of erythropoietin synthesizing cells in murine kineys by in situ hybridization," *Concise Report, Blood*, **1988**, *71(2)*, 524-527
EXAMINER		**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. JJPR-0048	Application No. 10/775,928
	Applicant Wing K. Cheung, et al.	
	Filing Date February 10, 2004	Group 1614
	Confirmation No. 1406	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	11	Lin, F.-K., et al., "Cloning and expression of the human erythropoietin gene," *Proc. Natl. Acad. Sci. USA*, **1985**, *82*, 7580-7584
	12	Markham, A., et al., "Epoetin alfa: A review of its pharmacodynamic and pharmacokinetic properties and therapeutic use in nonrenal applications," *Drugs*, **1995**, *49(2)*, 232-254
	13	McMahon, G.F., et al., "Pharmacokinetics and effects of recombinant human erythropoietin after intravenous subcutaneous injections in healthy volunteers," *Blood*, **1990**, *76(9)*, 1718-1722
	14	Salmonson, T., et al., "The pharmacokinetics of recombinant human erythropeitin after intravenous and subcutaneous administration to healthy subjects," *Br. J. Clin. Pharmac.*, **1990**, *29*, 709-713
EXAMINER		**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. JJPR-0048	Application No. 10/775,928
	Applicant Wing K. Cheung, et al.	
	Filing Date February 10, 2004	Group 1614
	Confirmation No. 1406	

U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass
	15	4,806,524	02/21/89	Kawaguchi, et al.	514	8
	16	4,879,272	11/07/89	Shimoda, et al.	514	8
	17	4,992,419	02/12/91	Woog, et al.	514	8
	18	5,376,632	12/27/94	Konings, et al.	514	8
	19	5,661,125	08/26/97	Strickland, et al.	514	8
	20	5,935,566	08/10/99	Yuen	424	85
	21	6,120,761	09/19/00	Yamazaki, et al.	424	85
	22	6,696,056	02/24/04	Cheung, et al.	424	85.1
	23	5,543,575	08/06/96	Wright, et al.	800	200
	24	5,688,679	11/18/97	Powell	435	240.2

FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation YES	Translation NO
	25	0 366 277 Equiv. of RU 2 122 403	05/1990	EPO		
	26	2 122 403 Equiv. of EP 0 366 277	11/1998	RU		
	27	WO 97/40850	11/1997	PCT		
	28	WO 97/48411	12/1997	PCT		

EXAMINER	**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. JJPR-0048	Application No. 10/775,928
	Applicant Wing K. Cheung, et al.	
	Filing Date February 10, 2004	Group 1614
	Confirmation No. 1406	

U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass

FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation YES	Translation NO
	29	6 40 619 B1	07/23/97	PCT		
	30	WO 94/12650 A2	06/09/94	PCT		
	31	WO 98/05363	02/12/98	PCT		
	32	WO 99/05268 A1	02/04/99	PCT		
	33	WO 99/11781 A1	03/11/99	PCT		
	34	WO 99/38890	08/05/99	PCT		
	35	WO 99/66054 A2	12/23/99	PCT		

EXAMINER	**DATE CONSIDERED**